STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
ATTORNEYS AT LAW
1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934

Facsimile Cover Sheet

urgent ☐ return reply requested ☐ original will be sent as confirmation ☐

DATE: May 9, 2002 **FAX NO.:** 703 746 5116

PAGES: 43 (including this cover sheet)

TO: **UNITED STATES PATENT AND TRADEMARK OFFICE**

ATTN: Examiner G. Shameem, Group Art Unit 1626

FROM: John M. Covert THN

RE: U.S. Patent Application
Appl. No. 09/814,123; Filed: March 22, 2001
For: **Aryl Substituted Pyrazoles, Triazoles and Tetrazoles, and the Use Thereof**
Inventors: Hogenkamp *et al.*

OUR REF: 1861.1270001/JMC/THN

MESSAGE

Further to your telephone conversation of today with Tarja Naukkarinen of our office, enclosed are the following documents for your review:

1) Copy of date-stamped receipt card, originally filed December 13, 2001, via hand carry;
2) Copy of SKGF Cover Letter, originally filed December 13, 2001, via hand carry;
3) Copy of Fee Transmittal Form (PTO/SB/17), originally filed December 13, 2001, via hand carry;
4) Copy of Amendment and Reply Under 37 C.F.R. § 1.111, originally filed December 13, 2001, via hand carry;
5) Copy of Information Disclosure Statement, originally filed December 13, 2001, via hand carry; and
6) Copy of Form PTO-1449 (16 sheets), originally filed December 13, 2001, via hand carry.

Please do not hesitate to contact us if you have any questions regarding this matter.

If any portion of this transmission is not received clearly or in full, contact us at any of the following numbers:

TELEPHONE NUMBER
(202) 371-2600

FACSIMILE NUMBER
(202) 371-2540

* * * COMMUNICATION RESULT REPORT (MAY. 9. 2002 4:01PM) * * *

TTI S. K. G. F.

FILE MODE	OPTION	ADDRESS (GROUP)	RESULT	PAGE
7010 MEMORY TX		6848#18611270001#7037465116#	OK	43/43

REASON FOR ERROR
E-1) HANG UP OR LINE FAIL
E-2) BUSY
E-3) NO ANSWER
E-4) NO FACSIMILE CONNECTION

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DATE: May 9, 2002 **FAX NO.:** 703 746 5116

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TO: UNITED STATES PATENT AND TRADEMARK OFFICE

ATTN: Examiner G. Shameem, Group Art Unit 1626

FROM: John M. Covert

RE: U.S. Patent Application
Appl. No. 09/814,123; Filed: March 22, 2001
For: **Aryl Substituted Pyrazoles, Triazoles and Tetrazoles, and the Use Thereof**
Inventors: Hogenkamp *et al.*

		Due Date:	**December 13, 2001**
Applicants:	Hogenkamp *et al.*	**Art Unit:**	1626
		Examiner:	Shameem, G.
Application No.:	09/814,123	**Docket:**	1861.1270001
Filed:	March 22, 2001	**Atty:**	JMC/THN

For: Aryl Substituted Pyrazoles, Triazoles and Tetrazoles, and the Use Thereof

When receipt stamp is placed hereon, the USPTO acknowledges receipt of the following documents:

1. SKGF Cover Letter (*in duplicate*);
2. Fee Transmittal Form (PTO/SB/17) (*in duplicate*);
3. Amendment and Reply Under 37 C.F.R. § 1.111;
4. Information Disclosure Statement (*in duplicate*);
5. Form PTO-1449 (16 sheets);
6. Copies of seventy-one (71) cited documents;
7. Our Check No. 33531 in the amount of $420.00 to cover the following fees: $72.00 Claims in excess of twenty (37 C.F.R. § 1.16(c)); $168.00 Independent claims in excess of three (37 C.F.R. § 1.16(b)); $180.00 Submission of an Information Disclosure Statement (37 C.F.R. § 1.17(p)); and
8. One (1) return postcard.

December 13, 2001

Via Hand Carry
Group Art Unit 1626
Examiner G. Shameem

Please Date Stamp And Return To Our Courier

6. Our Check No. 33531 in the amount of $420.00 to cover the following fees:

$ 72.00	Claims in excess of twenty (37 C.F.R. § 1.16(c));
$168.00	Independent claims in excess of three (37 C.F.R. § 1.16(b));
$180.00	Submission of an Information Disclosure Statement (37 C.F.R. § 1.17(p)); and

7. One (1) return postcard.

It is respectfully requested that the attached postcard be stamped with the date of filing of these documents, and that it be returned to our courier. In the event that extensions of time are necessary to prevent abandonment of this patent application, then such extensions of time are hereby petitioned.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this letter is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

John M. Covert

John M. Covert
Attorney for Applicants
Registration No. 38,759

Enclosures

P:\USERS\TARJAHN\1861\1861.1270001\pto\REPLY.111&IDS.TRANS.WPD

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
ATTORNEYS AT LAW
1100 NEW YORK AVENUE, N.W. • WASHINGTON, D.C. 20005-3934

PHONE: (202) 371-2600 • FACSIMILE: (202) 371-2540 • www.skgf.com

December 13, 2001

WRITER'S DIRECT NUMBER:
(202) 371-2673
INTERNET ADDRESS:
JCOVERT@SKGF.COM

Via Hand Carry
Group Art Unit 1626
Examiner G. Shameem

Commissioner for Patents
Washington, D.C. 20231

Re: U.S. Utility Patent Application
Appl. No. 09/814,123; Filed: March 22, 2001
For: **Aryl Substituted Pyrazoles, Triazoles and Tetrazoles, and the Use Thereof**
Inventors: Hogenkamp *et al.*
Our Ref: 1861.1270001/JMC/THN

Sir:

Transmitted herewith for appropriate action are the following documents:

1. Fee Transmittal Form (PTO/SB/17) (*in duplicate*);

2. Amendment and Reply Under 37 C.F.R. § 1.111;

3. Information Disclosure Statement (*in duplicate*);

4. Form PTO-1449 (16 sheets);

5. Copies of seventy-one (71) cited documents;

PTO/SB/17 (10-01)
Approved for use through 10/31/2002. OMB 0651-0032
Patent and Trademark Office: U.S. DEPARTMENT OF COMMERCE

FEE TRANSMITTAL for FY 2002

Patent fees are subject to annual revision.

TOTAL AMOUNT OF PAYMENT	($) 420.00

Complete If Known	
Application Number	09/814,123
Filing Date	March 22, 2001
First Named Inventor	Derk J. Hogenkamp
Examiner Name	Shameem, G.
Group Art Unit	1626
Attorney Docket No.	1861.1270001/JMC/THN

METHOD OF PAYMENT (check one)

1. ☐ The Commissioner is hereby authorized to charge indicated fees and credit any overpayment to:

Deposit Account Number	19-0036
Deposit Account Name	Sterne, Kessler, Goldstein & Fox P.L.L.C.

☐ Charge Any Additional Fee Required Under 37 CFR §§ 1.16 and 1.17

☐ Applicant claims small entity status See 37 CFR 1.27

2. ☒ Payment Enclosed:

☒ Check ☐ Credit card ☐ Money Order ☒ Other*

*Charge any deficiencies or credit any overpayments in the fees or fee calculations of Parts 1, 2 and 3 below to Deposit Account No. 19-0036.

FEE CALCULATION

1. BASIC FILING FEE

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee Paid
101	740	201	370	Utility filing fee	
106	330	206	165	Design filing fee	
107	510	207	255	Plant filing fee	
108	740	208	370	Reissue filing fee	
114	160	214	80	Provisional filing fee	

SUBTOTAL (1) ($) 0.00

2. EXTRA CLAIM FEES

	Extra	Fee from below	Fee Paid
Total Claims 29 - 25** =	4	X 18 =	72.00
Indep. Claims 7 - 5** =	2	X 84 =	168.00
Multiple Dependent		=	

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description
103	18	203	9	Claims in excess of 20
102	84	202	42	Independent claims in excess of 3
104	280	204	140	Multiple dependent claim
108	84	209	42	**Reissue independent claims over original patent
110	18	210	9	**Reissue claims in excess of 20 and over original patent

SUBTOTAL (2) ($) 240.00

** or number previously paid, if greater; For Reissues, see above

FEE CALCULATION (continued)

3. ADDITIONAL FEES

Large Entity Fee Code	Large Entity Fee ($)	Small Entity Fee Code	Small Entity Fee ($)	Fee Description	Fee paid
105	130	205	65	Surcharge - late filing fee or oath	
127	50	227	25	Surcharge - late provisional filing fee or cover sheet	
139	130	139	130	Non-English specification	
147	2,520	147	2,520	For filing a request for *ex parte* reexamination	
112	920*	112	920*	Requesting publication of SIR prior to Examiner action	
113	1,840*	113	1,840*	Requesting publication of SIR after Examiner action	
115	110	215	55	Extension for reply within first month	
116	400	216	200	Extension for reply within second month	
117	920	217	460	Extension for reply within third month	
118	1,440	218	720	Extension for reply within fourth month	
128	1,960	228	980	Extension for reply within fifth month	
119	320	219	160	Notice of Appeal	
120	320	220	160	Filing a brief in support of an appeal	
121	280	221	140	Request for oral hearing	
138	1,510	138	1,510	Petition to institute a public use proceeding	
140	110	240	55	Petition to revive - unavoidable	
141	1,280	241	640	Petition to revive - unintentional	
142	1,280	242	640	Utility issue fee (or reissue)	
143	460	243	230	Design issue fee	
144	620	244	310	Plant issue fee	
122	130	122	130	Petitions to the Commissioner	
123	130	123	130	Petitions related to provisional applications	
126	180	126	180	Submission of Information Disclosure Stmt	180.00
581	40	481	40	Recording each patent assignment per property (times number of properties)	
146	740	246	370	Filing a submission after final rejection (37 CFR 1.129(a))	
149	740	249	370	For each additional invention to be examined (37 CFR 1.129(b))	
179	740	279	370	Request for Continued Examination (RCE)	
169	900	169	900	Request for expedited examination of a design application	
Other fee (specify) :					
Other fee (specify) :					

*Reduced by Basic Filing Fee Paid

SUBTOTAL (3) ($) 180.00

SUBMITTED BY

Name (Print/Type)	John M. Covert	Registration No. (Attorney/Agent)	38,759	Telephone	202-371-2600
Signature	John M. Covert			Date	Dec. 13, 2001

WARNING: Information on this form may become public. Credit card information should not be included on this form. Provide credit card information and authorization on PTO-2038.

Burden Hour Statement: This form is estimated to take 0.2 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, Patent and Trademark Office, Washington, DC 20231. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Assistant Commissioner for Patents, Washington, DC 20231.

SKGF Rev. 10/01/01 mnac

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:	
HOGENKAMP *et al.*	Art Unit: 1626
Appl. No. 09/814,123	Examiner: Shameem, G.
Filed: March 22, 2001	Atty. Docket: 1861.1270001/JMC/THN
For: **Aryl Substituted Pyrazoles, Triazoles and Tetrazoles, and the Use Thereof**	

Amendment and Reply Under 37 C.F.R. §1.111

Commissioner for Patents
Washington, D.C. 20231

Sir:

In reply to the Office Action dated September 13, 2001 (PTO Prosecution File Wrapper Paper No. 4), Applicants submit the following Amendment and Remarks. This Amendment is provided in the following format:

(A) A clean version of each replacement paragraph/section/claim along with clear instructions for entry;

(B) Starting on a separate page, appropriate remarks and arguments. 37 C.F.R. § 1.111 and MPEP 714; and

(C) Starting on a separate page, a marked-up version entitled: "Version with markings to show changes made."

It is not believed that extensions of time or fees for net addition of claims are required beyond those that may otherwise be provided for in documents accompanying this paper. However, if additional extensions of time are necessary to prevent abandonment of this application, then such extensions of time are hereby petitioned under 37 C.F.R. § 1.136(a), and any fees required therefor (including fees for net

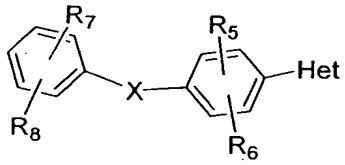
addition of claims) are hereby authorized to be charged to our Deposit Account No. 19-0036.

Amendments

In the Claims:

Please substitute the following claim 1 for the pending claim 1:

1. (Once amended) A compound having the Formula ***I***:

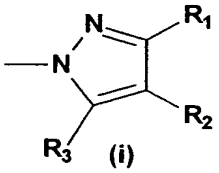


I

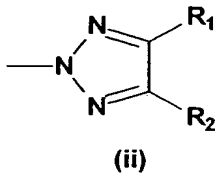
or a pharmaceutically acceptable salt, prodrug or solvate thereof, wherein

X is one of O, S, NR_9, or CH_2, where R_9 is hydrogen or C_1-C_{10} alkyl;

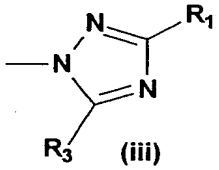
Het is a heteroaryl selected from the group consisting of



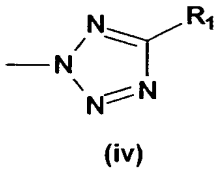
(i)



(ii)



(iii)



(iv)

R_1 is selected from the group consisting of hydrogen, optionally substituted alkyl, heteroaryl optionally substituted with one or more groups independently selected from the group consisting of halo, halo(C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, amino(C_{1-6})alkyl, hydroxy, nitro, C_{1-6} alkyl, C_{1-6} alkoxy, aminocarbonyl, carbamoyloxy, C_{1-6} alkylsulfonylamino, C_{1-6} acyl and amino, $C(O)R_{10}$, $CH_2C(O)R_{10}$, $S(O)R_{10}$, and SO_2R_{10};

R_2 and R_3 are independently selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, aryl, cyano, aminoalkyl, hydroxyalkyl, alkoxyalkyl, alkylthio,

alkylsulfinyl, alkylsulfonyl, carboxyalkyl, alkylamino, dialkylamino, aminocarbonyl, alkylaminocarbonyl, arylaminocarbonyl, aralkylaminocarbonyl, alkylcarbonylamino, arylcarbonylamino, aralkylcarbonylamino, alkylcarbonyl, aminosulfonyl, alkylaminosulfonyl, and alkylsulfonyl;

R_5, R_6, R_7, and R_8 are independently selected from the group consisting of hydrogen, halo, haloalkyl, alkyl, alkenyl, alkynyl, hydroxyalkyl, aminoalkyl, carboxyalkyl, alkoxyalkyl, nitro, amino, ureido, cyano, acylamino, amide, hydroxy, thiol, acyloxy, azido, alkoxy, carboxy, carbonylamido and alkylthiol;

R_{10} is selected from the group consisting of amino, alkyl, alkenyl, alkynyl, OR_{11}, alkylamino, dialkylamino, alkenylamino, dialkylaminoalkenyl, cycloalkyl, heterocycle, heteroaryl, aryl, aralkyl, arylalkenyl, arylalkynyl, and cycloalkylalkylamino;

R_{11} is selected from the group consisting of hydrogen, optionally substituted alkyl, and an alkalimetal; and

provided that:

1) when Het is (ii), and X is O, then R_{10} is not alkyl, aralkyl, aryl or OR_{11};
2) when Het is (i) or (ii), then X is not NR_9;
3) when Het is (iii), then X is not CH_2; and
4) when Het is (iii), and X is O, then R_{10} is not OR_{11}.

Please substitute the following claim 10 for the pending claim 10:

10. (Once Amended) A compound of claim 9, wherein:

R_5 and R_6 are each hydrogen;

R_3 and R_2 are both H; and

R_7 and R_8 are selected from the group consisting of hydrogen, halo, halo(C_1-C_6)alkyl, C_1-C_6 alkyl, hydroxy(C_1-C_6)alkyl, amino(C_1-C_6)alkyl, carboxy(C_1-C_6)alkyl, alkoxy(C_1-C_6)alkyl, nitro, amino, C_1-C_6 acylamino, amide, hydroxy, thiol, C_1-C_6 acyloxy, C_1-C_6 alkoxy, carboxy, carbonylamido and C_1-C_6 alkylthiol.

Please substitute the following claim 15 for the pending claim 15:

15. (Once Amended) A compound of claim 1, wherein:

Het is (i), (ii), (iii) or (iv);

R_1 is $C(O)R_{10}$, $CH_2C(O)R_{10}$, or SO_2R_{10};

X is O or S;

R_{10} is amino, optionally substituted C_1-C_6 alkyl, or a heterocycle selected from the group consisting of N-morpholinyl, N-pyrrolidinyl and N-piperazinyl;

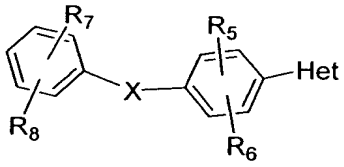
R_2, and R_3 are independently hydrogen, C_1-C_6 alkyl, C_1-C_6 alkylthio or C_1-C_6 alkylsulfinyl,

R_5 and R_6 are as defined in claim 1, and

R_7 and R_8 are independently selected from the group consisting of hydrogen, halo, halo(C_1-C_6)alkyl, C_1-C_6 alkyl, hydroxy(C_1-C_6)alkyl, amino(C_1-C_6)alkyl, carboxy(C_1-C_6)alkyl, alkoxy(C_1-C_6)alkyl, nitro, amino, C_1-C_6 acylamino, amide, hydroxy, thiol, C_1-C_6 acyloxy, C_1-C_6 alkoxy, carboxy, carbonylamido and C_1-C_6 alkylthiol.

Please substitute the following claim 16 for the pending claim 16:

16. (Once Amended) A compound of Formula *I*:

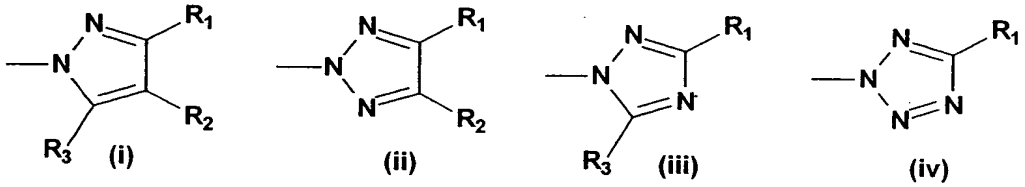


I

or a pharmaceutically acceptable salt, prodrug or solvate thereof, wherein

X is O or S;

Het is a heteroaryl selected from the group consisting of



R_1 is $C(O)R_{10}$, $CH_2C(O)R_{10}$, or SO_2R_{10} wherein R_{10} is amino, alkyl, N-morpholinyl, N-pyrrolidinyl or N-piperazinyl, all of which are optionally substituted;

R_2 and R_3 are independently hydrogen, C_1-C_6 alkyl, C_1-C_6 alkylthio or C_1-C_6 alkylsulfinyl;

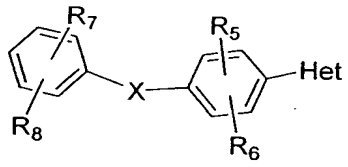
R_5, R_6, R_7 and R_8 are independently selected from the group consisting of hydrogen, halo, halo(C_1-C_6)alkyl, C_1-C_6 alkyl, hydroxy(C_1-C_6)alkyl, amino(C_1-C_6)alkyl, carboxy(C_1-C_6)alkyl, alkoxy(C_1-C_6)alkyl, nitro, amino, C_1-C_6 acylamino, amide, hydroxy, thiol, C_1-C_6 acyloxy, C_1-C_6 alkoxy, carboxy, carbonylamido and C_1-C_6 alkylthiol;

provided that:

1) when Het is (ii), and X is O, then R_{10} is not alkyl, aralkyl, aryl or OR_{11}; and
2) when Het is (iii), and X is O, then R_{10} is not OR_{11}.

Please substitute the following claim 22 for the pending claim 22:

22. (Once Amended) A compound of Formula *I*:

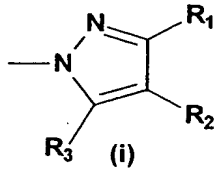


I

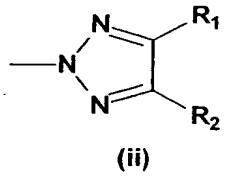
or a pharmaceutically acceptable salt, prodrug or solvate thereof, wherein

X is O or S;

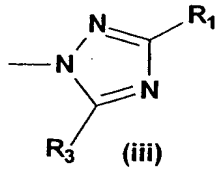
Het is a heteroaryl selected from the group consisting of



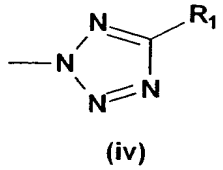
(i)



(ii)



(iii)



(iv)

R_1 is $C(O)R_{10}$, wherein R_{10} is amino, N-morpholinyl, N-pyrrolidinyl or N-piperazinyl, all of which are optionally substituted

R_2 and R_3 are independently hydrogen, C_1-C_6 alkyl, C_1-C_6 alkylthio or C_1-C_6 alkylsulfinyl;

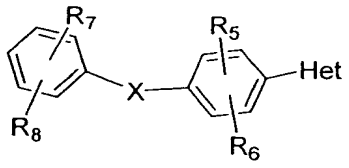
R_5, R_6, R_7 and R_8 are independently selected from the group consisting of hydrogen, halo, halo(C_1-C_6)alkyl, C_1-C_6 alkyl, hydroxy(C_1-C_6)alkyl, amino(C_1-C_6)alkyl,

carboxy(C_1-C_6)alkyl, alkoxy(C_1-C_6)alkyl, nitro, amino, C_1-C_6 acylamino, amide, hydroxy, thiol, C_1-C_6 acyloxy, C_1-C_6 alkoxy, carboxy, carbonylamido and C_1-C_6 alkylthiol.

Please insert the following claims 24-27:

24. (New) A compound of claim 15, wherein R_5 and R_6 are both hydrogen.

25. (New) A compound having the Formula *I*:

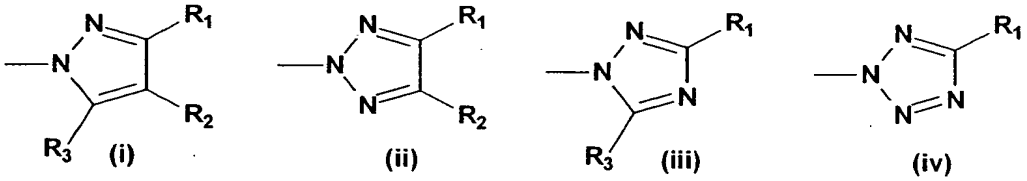


I

or a pharmaceutically acceptable salt, prodrug or solvate thereof, wherein

X is $NR_9C(O)$ or $C(O)NR_9$, where R_9 is hydrogen or C_1-C_{10} alkyl;

Het is a heteroaryl selected from the group consisting of



R_1 is SO_2R_{10};

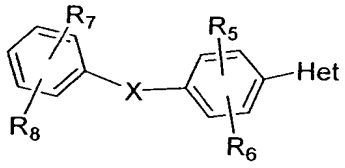
R_2 and R_3 are independently selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, aryl, cyano, aminoalkyl, hydroxyalkyl, alkoxyalkyl, alkylthio, alkylsulfinyl, alkylsulfonyl, carboxyalkyl, alkylamino, dialkylamino, aminocarbonyl, alkylaminocarbonyl, arylaminocarbonyl, aralkylaminocarbonyl, alkylcarbonylamino, arylcarbonylamino, aralkylcarbonylamino, alkylcarbonyl, aminosulfonyl, alkylaminosulfonyl, and alkylsulfonyl;

R_5, R_6, R_7, and R_8 are independently selected from the group consisting of hydrogen, halo, haloalkyl, alkyl, alkenyl, alkynyl, hydroxyalkyl, aminoalkyl, carboxyalkyl, alkoxyalkyl, nitro, amino, ureido, cyano, acylamino, amide, hydroxy, thiol, acyloxy, azido, alkoxy, carboxy, carbonylamido and alkylthiol;

R_{10} is selected from the group consisting of amino, alkyl, alkenyl, alkynyl, OR_{11}, alkylamino, dialkylamino, alkenylamino, dialkylaminoalkenyl, cycloalkyl, heterocycle, heteroaryl, aryl, aralkyl, arylalkenyl, arylalkynyl, and cycloalkylalkylamino; and

R_{11} is selected from the group consisting of hydrogen, optionally substituted alkyl, and an alkalimetal.

26. (New) A compound having the Formula *I*:

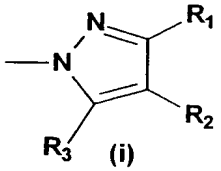


I

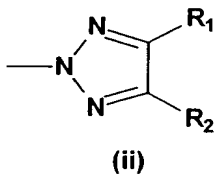
or a pharmaceutically acceptable salt, prodrug or solvate thereof, wherein

X is one of O, S, NR_9, CH_2, $NR_9C(O)$, or $C(O)NR_9$, where R_9 is hydrogen or C_1-C_{10} alkyl;

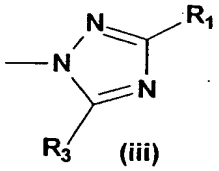
Het is a heteroaryl selected from the group consisting of



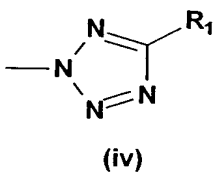
(i)



(ii)



(iii)



(iv)

R_1 is selected from the group consisting of hydrogen, optionally substituted alkyl, optionally substituted heteroaryl, $C(O)R_{10}$, $CH_2C(O)R_{10}$, $S(O)R_{10}$, and SO_2R_{10};

R_2 and R_3 are independently selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, aryl, cyano, aminoalkyl, hydroxyalkyl, alkoxyalkyl, alkylthio, alkylsulfinyl, alkylsulfonyl, carboxyalkyl, alkylamino, dialkylamino, aminocarbonyl, alkylaminocarbonyl, arylaminocarbonyl, aralkylaminocarbonyl, alkylcarbonylamino, arylcarbonylamino, aralkylcarbonylamino, alkylcarbonyl, aminosulfonyl,

alkylaminosulfonyl, and alkylsulfonyl;

R_5, R_6, R_7, and R_8 are independently selected from the group consisting of hydrogen, halo, haloalkyl, alkyl, alkenyl, alkynyl, hydroxyalkyl, aminoalkyl, carboxyalkyl, alkoxyalkyl, nitro, amino, ureido, cyano, acylamino, amide, hydroxy, thiol, acyloxy, azido, alkoxy, carboxy, carbonylamido and alkylthiol;

R_{10} is selected from the group consisting of amino, alkyl, alkenyl, alkynyl, OR_{11}, alkylamino, dialkylamino, alkenylamino, dialkylaminoalkenyl, cycloalkyl, heterocycle, heteroaryl, aryl, aralkyl, arylalkenyl, arylalkynyl, and cycloalkylalkylamino;

R_{11} is selected from the group consisting of hydrogen, optionally substituted alkyl, and an alkalimetal; and

wherein said compound is ^{3}H or ^{14}C radiolabeled.

27. (New) The method according to claim 19, wherein the method is for treating, preventing or ameliorating neuronal loss following global or focal ischemia, treating or ameliorating neurodegenerative conditions, treating, preventing or ameliorating pain or tinnitus, treating, preventing or ameliorating manic depression, providing local anesthesia, treating arrhytmias, or treating convulsions.

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-27 are pending in the application, with claims 1, 16, 18, 19, 22, 25, and 26 being the independent claims. Claims 1, 10, 15, 16, and 22 are sought to be amended, and new claims 24-27 are sought to be inserted. Support for the amendments and new claims 24-27 can be found in the original specification and claims as filed. These changes are believed to introduce no new matter, and their entry is respectfully requested. Specifically, X is $NR_9C(O)$ or $C(O)NR_9$ have been removed from claim 1 to further distinguish the claimed compounds from compounds allegedly disclosed in PCT published Appl. No. WO 99/62885. Applicants submit that no new matter has been introduced by this amendment since deletion of individual members of Markush expression does not constitute new matter. See, *In re Johnson and Farnham*, 194 U.S.P.Q. 187 (CCPA 1977). Claim 1 has also been amended by replacing "optionally substituted heteroaryl" in the definitions for R_1 with --heteroaryl optionally substituted with one or more groups independently selected from the group consisting of halo, . . . , and amino-- to further distinguish the claimed compounds from compounds allegedly disclosed in German published Appl. No. DE 1 936 760. Support for this amendment can be found at paragraph [0031] of the specification as originally filed. "R_4" in claim 10 has been amended to read --R_2--. Support for this amendment can be found at paragraph [0038], line 2, of the specification. Further, an obvious error in claim 15 has been amended by replacing "(vi)" with --(iv)--.

Support for new claim 24 can be found in claim 15 as originally filed. New claim 25 is supported by originally filed claims 1 and 7, and paragraph [0037] of the specification. New claim 26 is supported by paragraphs [0017], [0096], and [0097] of the specification.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

Rejection under 35 U.S.C. § 112, second paragraph

The present claims 1-23 are rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. Applicants respectfully traverse this rejection.

According to the Examiner, the expressions "optionally substituted", "Het", "preferably", "can be", and "disorder responsive to" place no definite limits or boundaries on the claims. Applicants respectfully disagree. Applicants have amended claim 15 to remove the expression "preferably", and replaced the expression "can be" with --are-- in claims 16 and 22. With regard to the expression "optionally substituted" in claims 1, 2, 15, 16, 18, 19 and 22, Applicants respectfully submit that it would have been clear for a person skilled in the art at the time the application was filed that the expression "optionally substituted" means that a particular group is substituted or unsubstituted. See, *Ex parte Gordova*, 10 USPQ2d 1949 (B.P.A.I. 1988). Thus, Applicants respectfully submit that one skilled in the art would be able to ascertain the scope of protection defined by claims 1, 2, 15, 16, 18, 19, and 22 with regard to the expression "optionally substituted".

The expression "Het" is clearly defined in claims as a heteroaryl having a structure (i), (ii), (iii), or (iv) and, thus, would have been clear for a person skilled in the art. See, for example, claim 1, lines 6-7. Applicants respectfully submit that one skilled in the art would be able to ascertain the scope of protection defined by claims 1, 11-16, 18, 19, and 22 with regard to the expression "Het".

Applicants respectfully submit that the expression "disorder responsive to" in claim 18, which is the only claim containing this expression, would have been clear for a

person skilled in the art at the time the present application was filed. The specification describes in the beginning of paragraph [0091] that "[s]ince the compounds of Formula ***I*** are blockers of sodium (Na^+) channels, a number of diseases and conditions mediated by sodium ion influx can be treated employing these compounds." Further, paragraphs [0091], [0003] through [0007], and [0100] describe non-limiting examples of specific disorders responsive to the blockade of Na^+ channel activity. Applicants respectfully submit that one skilled in the art would be able to ascertain the scope of protection defined by claim 18 with regard to the expression "disorder responsive to".

In view of the above, reconsideration and withdrawal of the rejection under 35 U.S.C. § 112, second paragraph, of claims 1-23 are respectfully requested.

Rejection under 35 U.S.C. § 112, first paragraph

The Examiner has rejected claims 19-21 under 35 U.S.C. § 112, first paragraph, as allegedly containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or which it is most nearly connected, to make and/or use the invention without undue experimentation. Applicants respectfully traverse this rejection.

The Examiner alleges as follows:

> [c]laim 19-21, are directed to "preventing or ameliorating" of neurodegenerative conditions, manic depression, neuropathic pain etc. to a mammal in need thereof. The claims refer to "preventing" of neuronal damage while all of the support in the specification enables "treating" and not "preventing". Because of the high level of unpredictability associated with the "preventing" of neuronal damage a greater amount of evidentiary support is needed in order to fully satisfy the requirement of 35 U.S.C. § 112, first paragraph. The applicant needs to provide sufficient guidance regarding "how to use" the invention properly.

(Office Action, page 3, line 4 from the bottom of the page through page 4, line 2).

Applicants respectfully disagree. First, the Examiner is incorrect in grouping the conditions claimed to be prevented in claims 19-21 as neuronal damages. Second, Applicants respectfully submit that preventing neuronal loss following global and focal ischemia, preventing neurodegenerative conditions, preventing pain, including neuropathic, surgical or chronic pain, or tinnitus, preventing manic depression, or preventing seizure activity as claimed in claims 19-21 are enabled. Na^+ channel blockers, such as BW619C89 and lifarizine have been shown to be neuroprotective in animal models of global and focal ischemia (see paragraph [0004] of the specification). Thus, sodium channel blockers have been shown to prevent neuronal loss following global and focal ischemia.

Riluzole, a sodium channel blocker approved by FDA for the treatment of ALS, has been shown to prolong survival in a subset of patients with ALS (see paragraph [0006], lines 1-4).

It would have been clear for a person skilled in the art at the time the application was filed that compounds having sodium channel blocking activity can be used for preventing the sensation of pain, including neuropathic pain, surgical pain or chronic pain. Further, based on the similarities between chronic pain and tinnitus, it has been proposed that tinnitus should be viewed as a form of chronic pain sensation. Lignocaine and carbamazepine, that are known to act by blocking or modulating sodium channel activity, have been shown to be efficacious in treating tinnitus (see paragraph [0006], lines 14-17 of the specification).

In addition to having been used for the treatment of manic depression (see paragraph [0006], lines 13-14), carbamazepine has been shown to be effective as a prophylactic treatment for manic depression (Denicoff, K. D., *et al.*, *J. Clin. Psychiatry* *55*:70-76 (1994)). Anticonvulsants, such as lamotrigine, phenytoin and carbamazepine, are known to act by blocking or modulating sodium channel activity (see paragraph [0003] of the specification), and are also described to prevent epileptic seizures (Catterall, W.A., *Trends Pharmacol. Sci.* *8*:57-65 (1987)). Further, Example 4 of the

specification shows that compounds of the present invention exhibit protection against maximal electroshock-induced seizures (MES).

Also, the specification provides suitable doses for disorders responsive to the blockade of sodium channels in mammal in paragraphs [0113] and [0114]. Specifically, doses for treatment or prevention of neuronal loss in global or focal ischemia are provided in paragraph [0114].

Furthermore, it would have been clear for a person skilled in the art at the time the invention was made how to identify those in need of such prevention of a disorder. Claim 19 clearly recites *that neuronal loss following* global and focal ischemia is prevented, i.e., global or focal ischemia have already been diagnosed. Further, Applicants respectfully submit that it would be clear for the skilled artisan, i.e., a medical doctor, to identify the people who would have a potential of becoming afflicted with neurodegenerative conditions, pain, including neuropathic pain, surgical pain and chronic pain, tinnitus, manic depression, and seizure activity based on the medical history of the patient and, thus, prevent, e.g., manic depression or neurodegenerative conditions by administering a Na^+ channel blocker of the present invention.

In summary, Applicants submit that the specification provides sufficient guidance as to how to use the invention as recited in claims 19-21.

Moreover, the Examiner alleges as follows:

> [i]t has not been shown in the specification that the "preventing" of such disorders is accepted in the art as being predictive of the utility alleged, especially when absent of pharmacological data (testing protocol). Merely stating that the instant compounds are useful for "preventing" against neuronal damage does not establish the usefulness of an invention absent art-recognized correlation between such tests and the ultimate use. Identifying substances as objects for further use testing (speculative utility) is insufficient to provide enabling disclosure. See Brenner v. Manson, 148 USPQ689 or In re Kirk, 153 USPQ 48.

(Office Action, page 4, lines 2-9).

Applicants respectfully disagree. It is submitted that the PTO must have adequate support for its challenge to the credibility of Applicants' statements as to utility. *In re Bundy*, 209 USPQ 48 (CCPA 1981). Further, "[o]nly after the PTO provides evidence showing that one of ordinary skill in the art would reasonably doubt the asserted utility does the burden shift to the applicant to provide rebuttal evidence sufficient to convince such a person of the invention's asserted utility." *In re Brana*, 34 USPQ2d 1436 (Fed. Cir. 1995). Applicants respectfully submit that the Examiner fails to provide such adequate support.

Furthermore, the Examiner alleges at page 4, lines 9-12, of the Office Action that Applicants do not give sufficient direction or guidance in enabling these claims, and that the quantity of experimentation required to make and use the invention based on the content of the disclosure would therefore be undue because of the level of unpredictability associated with "preventing" of neuronal damage. Applicants respectfully disagree. In view of the above arguments, Applicants maintain that the specification teaches to one skilled in the art how to make and use the claimed invention without undue experimentation.

Reconsideration and withdrawal of the rejection of claims 19-21 under 35 U.S.C. § 112, first paragraph, are respectfully requested.

Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,
STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

John M. Covert
Attorney for Applicants
Registration No. 38,759

Date: Dec. 13, 2001

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

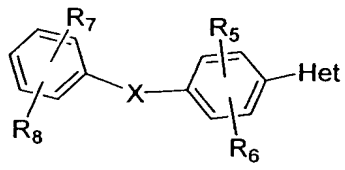
P107-12.doc

Version with markings to show changes made

New claims 24-27 have been inserted.

Claims 1, 10, 15, 16, and 22 have been amended as follows:

1. (Once Amended) A compound having the Formula *I*:

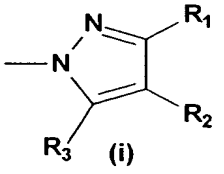


I

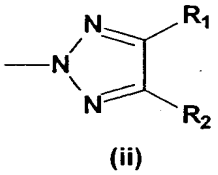
or a pharmaceutically acceptable salt, prodrug or solvate thereof, wherein

X is one of O, S, NR_9, or CH_2, [$NR_9C(O)$, or $C(O)NR_9$,] where R_9 is hydrogen or C_1-C_{10} alkyl;

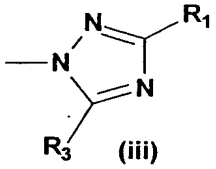
Het is a heteroaryl selected from the group consisting of



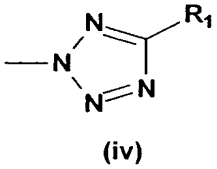
(i)



(ii)



(iii)



(iv)

R_1 is selected from the group consisting of hydrogen, optionally substituted alkyl, [optionally substituted] heteroaryl optionally substituted with one or more groups independently selected from the group consisting of halo, halo(C_{1-6})alkyl, hydroxy(C_{1-6})alkyl, amino(C_{1-6})alkyl, hydroxy, nitro, C_{1-6} alkyl, C_{1-6} alkoxy, aminocarbonyl, carbamoyloxy, C_{1-6} alkylsulfonylamino, C_{1-6} acyl and amino, $C(O)R_{10}$, $CH_2C(O)R_{10}$, $S(O)R_{10}$, and SO_2R_{10};

R_2 and R_3 are independently selected from the group consisting of hydrogen, alkyl, alkenyl, alkynyl, aryl, cyano, aminoalkyl, hydroxyalkyl, alkoxyalkyl, alkylthio, alkylsulfinyl, alkylsulfonyl, carboxyalkyl, alkylamino, dialkylamino, aminocarbonyl, alkylaminocarbonyl, arylaminocarbonyl, aralkylaminocarbonyl, alkylcarbonylamino, arylcarbonylamino, aralkylcarbonylamino, alkylcarbonyl, aminosulfonyl,

alkylaminosulfonyl, and alkylsulfonyl;

R_5, R_6, R_7, and R_8 are independently selected from the group consisting of hydrogen, halo, haloalkyl, alkyl, alkenyl, alkynyl, hydroxyalkyl, aminoalkyl, carboxyalkyl, alkoxyalkyl, nitro, amino, ureido, cyano, acylamino, amide, hydroxy, thiol, acyloxy, azido, alkoxy, carboxy, carbonylamido and alkylthiol;

R_{10} is selected from the group consisting of amino, alkyl, alkenyl, alkynyl, OR_{11}, alkylamino, dialkylamino, alkenylamino, dialkylaminoalkenyl, cycloalkyl, heterocycle, heteroaryl, aryl, aralkyl, arylalkenyl, arylalkynyl, and cycloalkylalkylamino;

R_{11} is selected from the group consisting of hydrogen, optionally substituted alkyl, and an alkalimetal; and

provided that:

1) when Het is (ii), and X is O, then R_{10} is not alkyl, aralkyl, aryl or OR_{11};
2) when Het is (i) or (ii), then X is not NR_9;
3) when Het is (iii), then X is not CH_2; and
4) when Het is (iii), and X is O, then R_{10} is not OR_{11}.

10. (Once Amended) A compound of claim 9, wherein:

R_5 and R_6 are each hydrogen;

R_3 and [R_4] $\underline{R_2}$ are both H; and

R_7 and R_8 are selected from the group consisting of hydrogen, halo, halo(C_1-C_6)alkyl, C_1-C_6 alkyl, hydroxy(C_1-C_6)alkyl, amino(C_1-C_6)alkyl, carboxy(C_1-C_6)alkyl, alkoxy(C_1-C_6)alkyl, nitro, amino, C_1-C_6 acylamino, amide, hydroxy, thiol, C_1-C_6 acyloxy, C_1-C_6 alkoxy, carboxy, carbonylamido and C_1-C_6 alkylthiol.

15. (Once Amended) A compound of claim 1, wherein:

Het is (i), (ii), (iii) or [(vi)] $\underline{(iv)}$;

R_1 is $C(O)R_{10}$, $CH_2C(O)R_{10}$, or SO_2R_{10};

X is O or S;

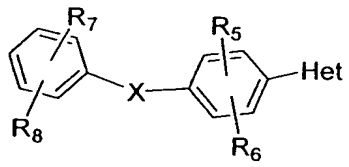
R_{10} is amino, optionally substituted C_1-C_6 alkyl, or a heterocycle selected from the group consisting of N-morpholinyl, N-pyrrolidinyl and N-piperazinyl;

R_2, and R_3 are independently hydrogen, C_1-C_6 alkyl, C_1-C_6 alkylthio or C_1-C_6 alkylsulfinyl,

R_5 and R_6 are as defined [above and are preferably hydrogen] in claim 1, and

R_7 and R_8 are independently selected from the group consisting of hydrogen, halo, halo(C_1-C_6)alkyl, C_1-C_6 alkyl, hydroxy(C_1-C_6)alkyl, amino(C_1-C_6)alkyl, carboxy(C_1-C_6)alkyl, alkoxy(C_1-C_6)alkyl, nitro, amino, C_1-C_6 acylamino, amide, hydroxy, thiol, C_1-C_6 acyloxy, C_1-C_6 alkoxy, carboxy, carbonylamido and C_1-C_6 alkylthiol.

16. (Once Amended) A compound of Formula *I*:

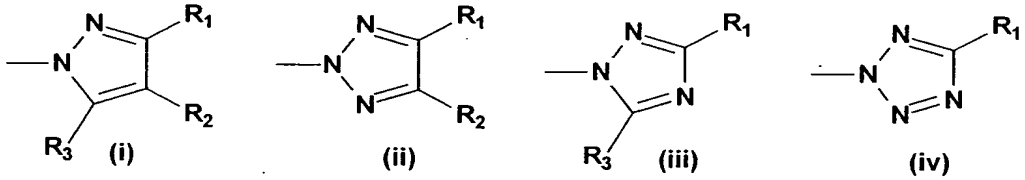


I

or a pharmaceutically acceptable salt, prodrug or solvate thereof, wherein

X is O or S;

Het is a heteroaryl selected from the group consisting of



R_1 is $C(O)R_{10}$, $CH_2C(O)R_{10}$, or SO_2R_{10} wherein R_{10} is amino, alkyl, N-morpholinyl, N-pyrrolidinyl or N-piperazinyl, all of which [can be] are optionally substituted;

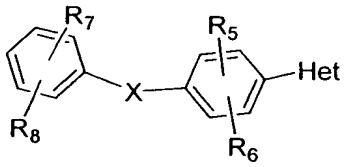
R_2 and R_3 are independently hydrogen, C_1-C_6 alkyl, C_1-C_6 alkylthio or C_1-C_6 alkylsulfinyl;

R_5, R_6, R_7 and R_8 are independently selected from the group consisting of hydrogen, halo, halo(C_1-C_6)alkyl, C_1-C_6 alkyl, hydroxy(C_1-C_6)alkyl, amino(C_1-C_6)alkyl, carboxy(C_1-C_6)alkyl, alkoxy(C_1-C_6)alkyl, nitro, amino, C_1-C_6 acylamino, amide, hydroxy, thiol, C_1-C_6 acyloxy, C_1-C_6 alkoxy, carboxy, carbonylamido and C_1-C_6 alkylthiol;

provided that:

1) when Het is (ii), and X is O, then R_{10} is not alkyl, aralkyl, aryl or OR_{11}; and
2) when Het is (iii), and X is O, then R_{10} is not OR_{11}.

22. (Once Amended) A compound of Formula ***I***:

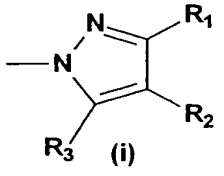


I

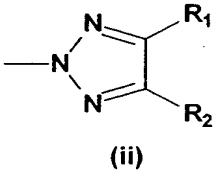
or a pharmaceutically acceptable salt, prodrug or solvate thereof, wherein

X is O or S;

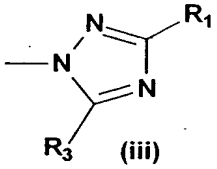
Het is a heteroaryl selected from the group consisting of



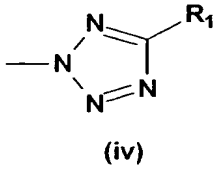
(i)



(ii)



(iii)



(iv)

R_1 is $C(O)R_{10}$, wherein R_{10} is amino, N-morpholinyl, N-pyrrolidinyl or N-piperazinyl, all of which [can be] <u>are</u> optionally substituted

R_2 and R_3 are independently hydrogen, C_1-C_6 alkyl, C_1-C_6 alkylthio or C_1-C_6 alkylsulfinyl;

R_5, R_6, R_7 and R_8 are independently selected from the group consisting of hydrogen, halo, halo(C_1-C_6)alkyl, C_1-C_6 alkyl, hydroxy(C_1-C_6)alkyl, amino(C_1-C_6)alkyl, carboxy(C_1-C_6)alkyl, alkoxy(C_1-C_6)alkyl, nitro, amino, C_1-C_6 acylamino, amide, hydroxy, thiol, C_1-C_6 acyloxy, C_1-C_6 alkoxy, carboxy, carbonylamido and C_1-C_6 alkylthiol.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Hogenkamp *et al.*	Confirmation No. 2060
Appl. No. 09/814,123	Art Unit: 1626
Filed: March 22, 2001	Examiner: Shameem, G.
For: **Aryl Substituted Pyrazoles, Triazoles and Tetrazoles, and the Use Thereof**	Atty. Docket: 1861.1270001/JMC/THN

Information Disclosure Statement

Commissioner for Patents
Washington, D.C. 20231

Sir:

Listed on accompanying Form PTO-1449 are documents that may be considered material to the examination of this application, in compliance with the duty of disclosure requirements of 37 C.F.R. §§ 1.56, 1.97 and 1.98.

In accordance with 37 C.F.R. § 1.98(a)(3), Applicants' undersigned representative submits the following, in regards to non-English language documents AL1 and AL2 cited on Form PTO 1449:

Document **AL1**, German Patent No. DE 19 36 760 is in the German language. An English language abstract of document AL1 is attached as document **AT15**.

Document **AM1**,German Patent No. DE 29 10 330 A1 is in the German language. An English language abstract of document AM1 is attached as document **AR16**.

Document **AL3**, Japanese Patent No. JP 11 199566 A is in the Japanese language. An English language abstract of document AL3 is attached as document **AS16**.

Where the publication date of a listed document does not provide a month of publication, the year of publication of the listed document is sufficiently earlier than the effective U.S. filing date and any foreign priority date so that the month of publication is not in issue. Applicants have listed publication dates on the attached PTO-1449 based on information presently available to the undersigned. However, the listed publication dates should not be construed as an admission that the information was actually published on the date indicated.

Applicants reserve the right to establish the patentability of the claimed invention over any of the information provided herewith, and/or to prove that this information may not be prior art, and/or to prove that this information may not be enabling for the teachings purportedly offered.

This statement should not be construed as a representation that a search has been made, or that information more material to the examination of the present patent application does not exist. The Examiner is specifically requested not to rely solely on the material submitted herewith.

This Information Disclosure Statement is being filed more than three months after the U.S. filing date AND after the mailing date of the first Office Action on the merits, but before the mailing date of a Final Rejection, or Notice of Allowance, or an action that otherwise closes prosecution in the application. Attached is our Check No. 33531 in the amount of $180.00 in payment of the fee under 37 C.F.R. § 1.17(p).

It is respectfully requested that the Examiner initial and return a copy of the enclosed PTO-1449, and indicate in the official file wrapper of this patent application that the documents have been considered.

The U.S. Patent and Trademark Office is hereby authorized to charge any fee deficiency, or credit any overpayment, to our Deposit Account No. 19-0036. A duplicate copy of this pleading is enclosed.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.

John M. Covert
Attorney for Applicants
Registration No. 38,759

Date: Dec. 13, 2001

1100 New York Avenue, N.W.
Suite 600
Washington, D.C. 20005-3934
(202) 371-2600

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1861.1270001/JMC/THN	APPLICATION NO. 09/814,123
	APPLICANT Hogenkamp *et al.*	
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U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA1	3,049,438	08/14/1962	Buell and Long	117	33.5	11/03/1958
	AB1	3,058,989	10/16/1962	Buell and Long	260	296	11/26/1957
	AC1	4,072,498	02/07/1978	Moon *et al.*	71	92	05/14/1976
	AD1	4,394,514	07/19/1983	Kruse, L.I.	548	508	06/29/1981
	AE1	4,454,337	06/12/1984	Kruse, L.I.	560	22	03/02/1983
	AF1	4,639,266	01/27/1987	Heubach *et al.*	71	92	09/09/1985
	AG1	4,962,011	10/09/1990	Aldag *et al.*	430	281	05/17/1988
	AH1	5,134,142	07/28/1992	Matsuo *et al.*	514	255	09/14/1990
	AI1	5,670,533	09/23/1997	Matsuo *et al.*	514	106	12/28/1995
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	AK						

FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL1	DE 19 36 760	01/22/1970	Germany			Abstract Yes No
	AM1	DE 29 10 330 A1	10/02/1980	Germany			Abstract Yes No
	AN1	GB 2 105 327 A	03/23/1983	Great Britain			Yes No
	AO1	EP 0 273 528 A1	07/06/1988	Europe			Yes No
	AP1	EP 0 323 841 A2	07/12/1989	Europe			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	1	Arient, J. and Dvořák, J., "Triphenylmethane dyes. II. Introduction of the triazole group into the triphenylmethane skeleton," *Chem. Abstracts 52*:Abstract No. 12401i, The American Chemical Society (1958).
	AS	1	Baud, J., *et al.*, "CGP 31358 binds to a site on the NMDA receptor that is coupled to both the transmitter recognition site and the channel domain," *Neurosci. Lett. 107*:184-188, Elsevier Scientific Publishers Ireland Ltd. (1989).
	AT	1	Bensimon, G., *et al.*, "A Controlled Trial of Riluzole in Amyotrophic Lateral Sclerosis," *New Eng. J. Med. 330*:585-591, Massachusetts Medical Society (1994).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL2	EP 0 323 841 A3	09/12/1990	Europe			Yes No
	AM2	EP 0 488 959 A2	06/03/1992	Europe			Yes No
	AN2	EP 0 323 841 B1	08/04/1993	Europe			Yes No
	AO2	WO 96/11911	04/25/1996	WIPO			Yes No
	AP2	WO 97/07102	02/27/1997	WIPO			Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	2	Brown, J.B. and Stammers, D.W., "Yellow color images by silver and dye bleaching," *Chem. Abstracts 57*:Abstract No. 12673d, The American Chemical Society (1962).
	AS	2	Brown, C.M., *et al.*, "Neuroprotective properties of lifarizine compared with those of other agents in a mouse model of focal cerebral ischaemia," *Br. J. Pharmacol. 115*:1425-1432, Stockton Press (August 1995).
	AT	2	Buchan, A.M., *et al.*, "AMPA Antagonists: Do They Hold More Promise for Clinical Stroke Trials Than NMDA Antagonists," *Suppl. I Stroke 24*:148-152, Lippincott Williams and Wilkins (1993).

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EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL3	JP 11 199566 A	07/27/1999	Japan			Abstract Yes No
	AM3	WO 99/62885	12/09/1999	WIPO			Yes No
	AN3	WO 00/57877	10/05/2000	WIPO			Yes No
	AO3	EP 1 081 146 A1	03/07/2001	Europe			Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	3	Catterall, W.A., "Structure and Function of Voltage-Sensitive Ion Channels," *Science 242*:50-61, American Association for the Advancement of Science (1988).
	AS	3	Catterall, W.A., "Neurotoxins That Act on Voltage-Sensitive Sodium Channels in Excitable Membranes," *Ann. Rev. Pharmacol. Toxicol 20*:15-43, Annual Reviews Inc. (1980).
	AT	3	Catterall, W.A., "Common modes of drug action on Na^+ channels: local anesthetics, antiarrhythmics and anticonvulsants," *Trends Pharmacol. Sci. 8*:57-65, Elsevier Science Publishers B.V. (1987).

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	4	Cocco, M.T., *et al.*, "Phytotoxic Activity in Pyrazole Derivatives II," *Il Farmaco Ed. Sc. 40*:272-284, Societa Italiana Di Scienze Farmaceutiche (1985).
	AS	4	Creveling, C.R., *et al.*, "Batrachotoxin-Induced Depolarization and [^{3}H] Batrachotoxinin-A 20α-Benzoate Binding in a Vesicular Preparation from Guinea Pig Cerebral Cortex," *Mol. Pharmacol. 23*:350-358, The American Society for Pharmacology and Experimental Therapeutics (1983).
	AT	4	Dal Monte, D. and Veggetti, P., "Derivatives of pyrazolone and pyrazolyl carbamates," *Chem. Abstracts 53*:Abstract No. 8122f, The American Chemical Society (1959).

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	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	5	Denicoff, K.D., *et al.*, "Efficacy of Carbamazepine Compared With Other Agents: A Clinical Practice Survey," *J. Clin. Psychiatry 55*:70-76, Physicians'Postgraduate Press, Inc. (1994).
	AS	5	Dimmock, J.R., *et al.*, "Evaluation of the thiosemicarbazones of some aryl alkyl ketones and related compounds for anticonvulsant activities," *Eur. J. Med. Chem. 26*:529-534, Elsevier Science (1991).
	AT	5	Donaldson, I., "Tegretol: A double blind trial in tinnitus," *J. Laryngol. Otol. 95*:947-951, Royal Society of Medicine Press (1981).

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	AL						Yes No
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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	6	Filer, C.N., "Chapter 6, The Preparation and Characterization of Tritiated Neurochemicals," *In:* Isotopes in the Physical and Biomedical Sciences, Volume 1, Labelled Compounds (Part A), Buncel, E. and Jones, J.R. eds., pp.156-192, Elsevier Science Publishers B.V. (1987).
	AS	6	J.R. Geigy A.-G., "Diazo dyes," *Chem. Abstracts 60*:Abstract No. 12144b, The American Chemical Society (1964).
	AT	6	Graham, S.H., *et al.*, "Neuroprotective Effects of a Use-Dependent Blocker of Voltage-Dependent Sodium Channels, BW619C89, in Rat Middle Cerebral Artery Occlusion," *J. Pharmacol. Exp. Ther. 269*:854-859, The American Society for Pharmacology and Experimental Therapeutics (1994).

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	7	Graham, S.H., *et al.*, "A Dose-Response Study of Neuroprotection Using the AMPA Antagonist NBQX in Rat Focal Cerebral Ischemia," *J. Pharmacol. Exp. Ther. 276*:1-4, The American Society for Pharmacology and Experimental Therapeutics (1996).
	AS	7	Hamill, O.P., *et al.*, "Improved Patch-Clamp Techniques for High-Resolution Current Recording from Cells and Cell-Free Membrane Patches," *Pflügers Arch. 391*:85-100, Springer-Verlag (1981).
	AT	7	Hunskaar, S. *et al.*,"Formalin test in mice, a useful technique for evaluating mild analgesics," *J. Neurosci. Methods 14*:69-76, Elsevier Science Publishers B.V.(1985).

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	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	8	Iwasaki, Y., *et al.*, "CNQX prevents spinal motor neuron death following sciatic nerve transection in newborn rats," *J. Neurosci. 134*:21-25, Elsevier Science B.V. (1995).
	AS	8	Kuo, C.-C. and Bean, B.P., "Slow Binding of Phenytoin to Inactivated Sodium Channels in Rat Hippocampal Neurons," *Mol. Pharmacol. 46*:716-725, The American Society for Pharmacology and Experimental Therapeutics (1994).
	AT	8	Lam, P.Y.S., *et al.*, "New Aryl/Heteroaryl C-N Bond Cross-coupling Reactions via Arylboronic Acid/Cupric Acetate Arylation," *Tetrahedron Lett. 39*:2941-2944, Elsevier Science Ltd. (1998).

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	AO						Yes No
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OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	9	Majumdar, B., *et al.*, "An electrocochleographic study of the effects of lignocaine on patients with tinnitus," *Clin. Otolaryngol 8*:175-180, Blackwell Scientific Publications (1983).
	AS	9	Magagnoli, R., "1-(p-Benzoylphenyl)-3-alkyl(or benzamido)-5-pyrazolones as color couplers," *Chem. Abstracts 65*:Abstract No. 5576g, The American Chemical Society (1966).
	AT	9	Møller, A.R., "Similarities Between Chronic Pain and Tinnitus," *Am. J. Otol. 18*:577-585, Lippincott-Raven Publishers (1997).

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	AR	10	Neeff, R., "Anilinoanthraquinone dyes," *Chem. Abstracts 63*:Abstract No. 11745g, The American Chemical Society (1965).
	AS	10	Ohizumi, Y., *et al.*, "Specific Inhibition of [^{3}H] Saxitoxin Binding to Skeletal Muscle Sodium Channels by Geographutoxin II, a Polypeptide Channel Blocker," *J. Biol. Chem. 261*:6149-6152, The American Society of Biological Chemists, Inc. (1986).
	AT	10	Pokorný, M. and Haase, J., "Substantive triphenodioxazine dyes containing a naphtho-[1,2-*d*] triazole nucleus," *Chem. Abstracts 55*:Abstract No. 7854i, The American Chemical Society (1961).

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	AR	11	Polevoi, L.G., *et al.*. "Relation of aminopyrazole structures to their neurotropic activity," retrieved from STN, Database Accession No. 69:1557 CAPLUS, Chemical Abstracts Service (1968).
	AS	11	Ragsdale, D.S., *et al.*, "Frequency and Voltage-Dependent Inhibition of Type IIA Na+ Channels, Expressed in a Mammalian Cell Line, by Local Anesthetic, Antiarrhythmic, and Anticonvulsant Drugs," *Mol. Pharmacol. 40*:756-765, Williams & Wilkins (1991).
	AT	11	Rasavi, D., "Reactive dyes," *Chem. Abstracts 59*:Abstract 6555g, The American Chemical Society (1963).

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	AO						Yes No
	AP						Yes No

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	AR	12	Sheardown, M.J., *et al.*, "AMPA, but not NMDA, receptor antagonism is neuroprotective in gerbil global ischaemia, even when delayed 24 h," *Eur. J. Pharmacol. 236*:347-353, Elsevier Science Publishers B.V. (1993).
	AS	12	Simpson, J.J., and Davies, W.E., "Recent advances in the pharmacological treatment of tinnitus," *Trends Pharmacol. Sci. 20*:12-18, Elsevier Science London (1999).
	AT	12	Steck, E.A., *et al.*, "Some Guanazole Derivatives," *J. Am. Chem. Soc. 80*:3929-3931, The American Chemical Society (1958).

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	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	13	Steck, E.A., and Nachod, F.C., "Absorption Spectra of Heterocyclic Compunds. VII. Some 3(2H)-Pyridazones," *J. Am. Chem. Soc.* *79*:4408-4411, The American Chemical Society (1957).
	AS	13	Stefancich, G., *et al.*, "Analogues of Bifonazole with Two Imidazole Moieties and Related Azoles," *Arch. Pharm. (Weinheim)* *323*:273-280, VCH Verlagsgesellschaft mbH (1990).
	AT	13	Stys, P.K., *et al.*, "Ionic Mechanisms of Anoxic Injury in Mammalian CNS White Matter: Role of Na^+ Channels and Na^+ -Ca^{2+} Exchanger," *J. Neurosci.* *12*:430-439, Society for Neuroscience (1992).

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FORM PTO-1449 INFORMATION DISCLOSURE STATEMENT	ATTY. DOCKET NO. 1861.1270001/JMC/THN	APPLICATION NO. 09/814,123
	APPLICANT Hogenkamp *et al.*	
	FILING DATE March 22, 2001	GROUP 1626

U.S. PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	NAME	CLASS	SUB-CLASS	FILING DATE
	AA						
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FOREIGN PATENT DOCUMENTS

EXAMINER INITIAL		DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB-CLASS	TRANSLATION
	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	14	Taylor, C.P., and Meldrum, B.S., "Na$^+$ channels as targets for neuroprotective drugs," *Trends Pharmacol. Sci. 16*:309-316, Elsevier Trends Journals (1995).
	AS	14	Tonndorf, J., "The analogy between tinnitus and pain: A suggestion for a physiological basis of chronic tinnitus," *Hear Res. 28*:271-275, Elsevier Science Publishers B.V. (1987).
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	AO						Yes No
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	AR	15	Wrathall, J.R., *et al.*, "Amelioration of Functional Deficits from Spinal Cord Trauma with Systemically Administered NBQX, an Antagonist of Non-N-methyl-D-aspartate receptors," *Exp. Neurol. 137*:119-126, Academic Press, Inc. (1996).
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	AL						Yes No
	AM						Yes No
	AN						Yes No
	AO						Yes No
	AP						Yes No

OTHER (Including Author, Title, Date, Pertinent Pages, etc.)

	AR	16	Dialog File 351, Accession No. 2553655, Derwent WPI English language abtract for DE 29 10 330 A1 (Document AM1).
	AS	16	Dialog File 351, Accession No. 12667941, Derwent WPI English Language abstract for JP 11 199566 A (Document AL3).
	AT	16	International Search Report for International Application No. PCT/US 01/08972, mailed September 24, 2001.

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